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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,925	01/31/2001	Steven Neville Chatfield	117-320	2850

7590

06/28/2002

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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/28/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/646,925

Applicant(s)

CHATFIELD, STEVEN NEVILLE

Examiner

Vanessa L. Ford

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Technically "use of" is non-statutory; however for the purposes of election it is being treated as a product only and thus placed in Group II.

#### **Election/Restrictions**

- |           |  |
|-----------|--|
| Group I   | Claims 1-11 and 13 are drawn to a bacterium attenuated by a non-reverting mutation in each of the <i>aroC</i> gene, the <i>ompF</i> gene and the <i>ompC</i> gene.                 |
| Group II  | Claims 12 and 15 are drawn to a vaccine comprising a bacterium comprising mutations in each of the <i>aroC</i> gene, the <i>ompF</i> gene and the <i>ompC</i> gene.                |
| Group III | Claim 14 is drawn to an enterotoxigenic <i>E. coli</i> cell attenuated by a non-reverting mutation in each of the <i>aroC</i> gene, the <i>ompF</i> gene and the <i>ompC</i> gene. |
| Group IV  | Claim 16 is drawn to a method of raising an immune response in a mammalian host which comprises administering to the host a bacterium  |

attenuated by a non-reverting mutation in each of the *aroC* gene, the *ompF* gene and the *ompC* gene.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I lacks novelty under PCT Article 33(2) as being unpatentable over Chatfield et al (*Infection and Immunity*, January 1991, p. 449-452) in view of Dougan et al (*The Journal of Infectious Diseases*, Vol. 158, No. 6, December 1988).

Chatfield et al teach a *Salmonella typhimurium* strain (SL1344) harboring stable mutations in both *ompC* and *ompF* (see the Abstract). Chatfield et al teach that the *ompC* and *ompF* double mutants of *Salmonella typhimurium* are useful as attenuated orally but shows little loss of virulence when given intravenously (see page 451, 2<sup>nd</sup> column). Chatfield et al do not teach a mutant in the *aroC* gene. Dougan et al teach mutations in the *aroC* and *aroA* gene of *Salmonella typhimurium* strain (SL3144). Dougan et al teach that fifty percent lethal doses after intravenous inoculation of mutants into BALB/C mice were determined and the *aroC* mutants were as highly attenuated as were the *aroA* mutants (see the Abstract). It would have been obvious at the time the invention was made to add the *aroC* mutants as taught by Dougan et al to the *ompC* and *ompF* mutants of Chatfield et al because Dougan et al teach that mutations in *aroC* genes are were highly attenuated after intravenous inoculation (see the Abstract).


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Group I is the main invention in this application and it lacks novelty, therefore the other claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

3. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
June 26, 2002

  
LYNETTE B. F. SMITH  
SUPERVISORY PATENT EXAMINER  
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